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(54) **Implantable correctant of spinal curvature**

(57) An implantable correctant of spinal curvature includes a single flat rod (1) of a resilient material, bent into an arcuate shape, positionable with its convex side facing the convexity of the spine (2), along the spinous processes (3) thereof, and securable on the spine (2) with the aid of a fixing device, so that the rod (1) is at least partly straightened to impart forces tending to straighten the spine (2).

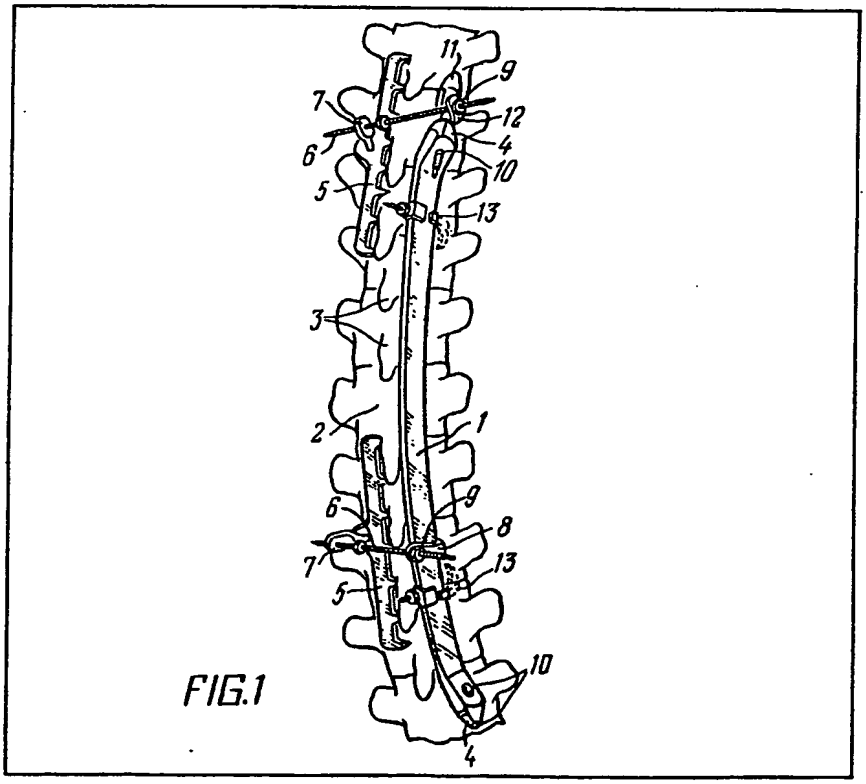

FIG.1

GB 2 109 238 A

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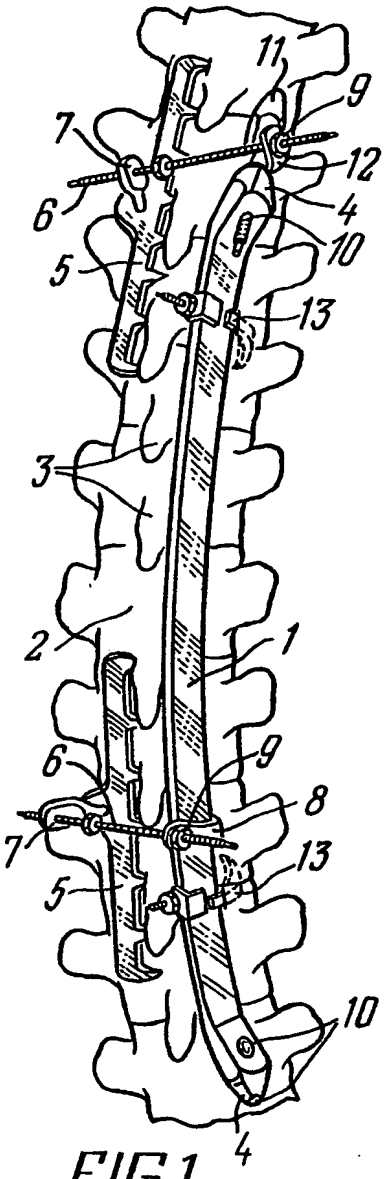

FIG.1

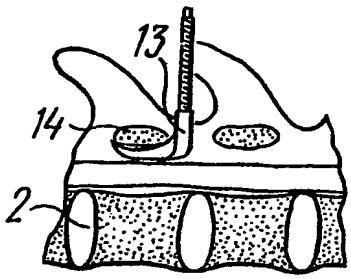

FIG.2

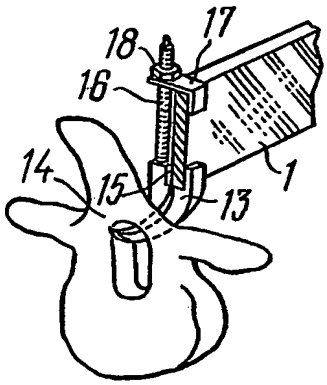

FIG.3

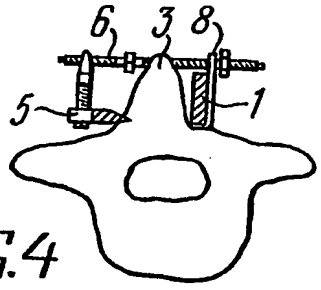

FIG.4

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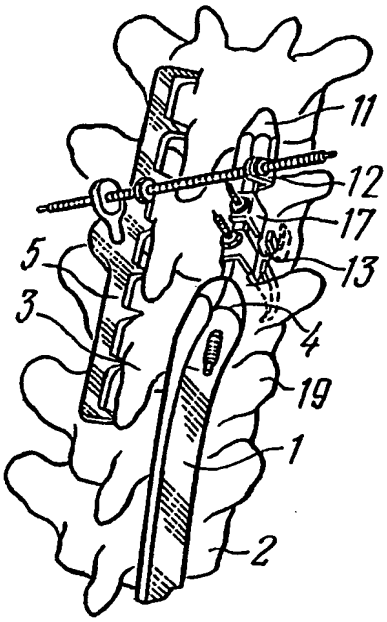

FIG.7

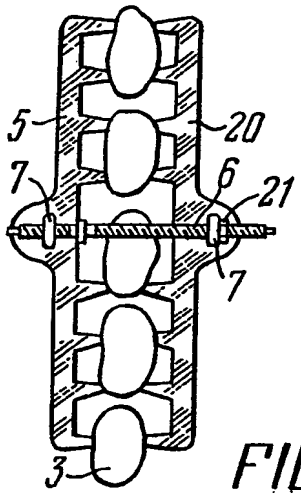

FIG.8

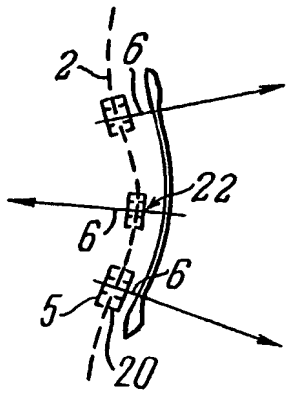

FIG.9

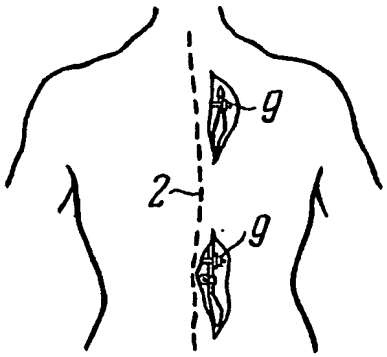

FIG.11

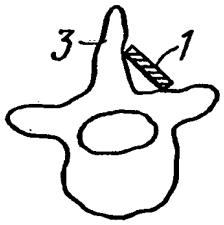

FIG.5

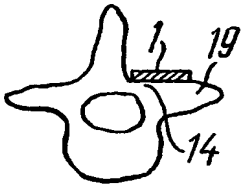

FIG.6

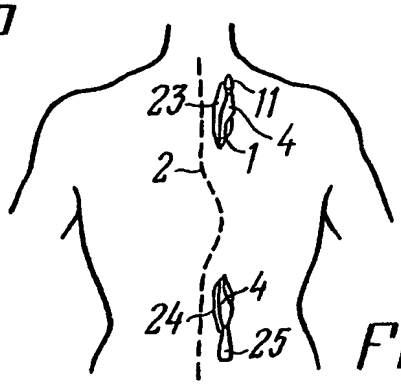

FIG.10

SPECIFICATION

Implantable correctant of spinal curvature

The present invention relates to medical instrumentation, and, more particularly, it relates to devices for treating the cases of spinal curvature, such as implantable correctants of spinal curvature.

An implantable correctant of spinal curvature is employed for treating the aggravating cases of scoliosis with the curvature angles up to 50° according to Cobb. It can be also employed for treating kyphoscoliosis, juvenile kyphosis, Calvé disease, Kümmel's traumatic spondylitis, new and inveterate spinal fractures accompanied by kyphotic deformation, and also in cases of scoliotic deformation with curvature angles exceeding 50° by Cobb.

The essence of the present invention resides in an implantable correctant of spinal curvature, having an arcuate shape and adapted to be placed with its convex side facing the convexity of the spine, longitudinally of the spinous processes, and retained thereon with aid of a fixing device, so that the correctant is partly straightened to create an effort straightening the spine, which correctant, in accordance with the present invention, includes a single flat rod of a resilient material, set to one side of the spinous processes.

In order to bring the rod against the spine by the enclosed technique, i.e. by pushing it through the soft tissues, its either one or both ends are preferaby made of a tapering shape, with the surface of the end portion on the convex side being the continuation of the surface of the rod, while the surface of the concave side defining a bevel merging with the concave surface of the rest of the rod.

To retain the spine in the frontal plane, the device for fixing the rod preferably includes two combs arranged at the end of the rod at the convex side thereof and having their teeth facing the rod, and braces in a number corresponding to that of the combs, for adjusting the spine-straightening effort, each brace having one its end connected with the rod and the other end connected with the respective comb.

In cases of particularly pronounced spinal curvature, it is expedient that the device for fixing the rod should include auxiliary combs in a number corresponding to that of the main combs, arranged intermediate the rod and the respective main combs with their teeth facing the teeth of the main combs, and secured on the braces of the respective main combs.

In order to retain the spine in the sagittal plane, it is expedient that the device for fixing the rod should include on each end portion of the rod either one or two hooks mounted to engage the arch of the respective vertebrae.

The ends of the rod, having the tapering shape, preferably have made therein oblong holes, in which case the device for fixing the rod includes screws receivable in these holes, the braces being secured directly on these screws for rotation about the rod.

In cases of a high degree of the curvature of the spine, it is further expedient that the device for fixing the rod should comprise an additional pair of combs extending parallel with the rod at the convex side of the central portion thereof, and a brace having one its end attached to the rod, the combs of the additional pair being mounted thereon with their teeth facing one another.

The present invention will be further described in connection with embodiments thereof, with reference being made to the accompanying drawings, wherein:

Figure 1 is a general view of an implantable correctant of spinal curvature fixed to the spine, in accordance with the invention;

Figure 2 is a longitudinally sectional view of a part of a vertebra in the sagittal plane, with the hook engaging the arch of the vertebra, according to the invention;

Figure 3 is a cross-sectional view of a vertebra, illustrating the arrangement of the hook and rod relative to the arch of the vertebra, according to the invention;

Figure 4 is a cross sectional view of a vertebra in the place where a comb is positioned, in accordance with the invention;

Figure 5 is a cross-sectional view of a vertebra and of the rod, illustrating the positioning of the rod relative to the spinal bone structures in kyphoscoliosis cases, in accordance with the invention;

Figure 6 is a view similar to Figure 5, in kyphosis cases;

Figure 7 shows the modified retaining of the rod on the spine in scoliosis cases, according to the invention;

Figure 8 shows a pair of the combs of the device for fixing the rod, positioned relative to the spinous processes, in accordance with the invention;

Figure 9 illustrates schematically the retaining of the rod on the spine with the use of the three pairs of combs, according to the invention;

Figure 10 illustrates a stage of a surgical operation of setting the correctant rod, prior to its fixation to the spine (the spine being still curved), according to the invention;

Figure 11 is a continuation of Figure 10, with the rod fixed in place (the spine is straightened), according to the invention.

Referring now to the appended drawings, the implantable correctant of spinal curvature includes a single flat rod 1 (Figure 1) having an arcuate shape. The rod 1 is made of a resilient material, e.g. a titanium alloy, and is set longitudinally of the spine 2 with its convex side facing the convexity of the spine 2, to one side of the latter's spinous processes 3; it is fixed on the spine with aid of a fixing device, so that the rod 1 is partly straightened to create an effort straightening up the spine 2. To correct the spine 2 in cases where the curvature angle is up to 50°C, it is necessary to apply an effort within a range of 400 to 600 N, and with the curvature in excess of 50°, the necessary effort may be as high as 1000 N and even higher, Preferably, the length of the rod 1 is 265 to 285 mm, its thickness being 1.5 to 2.0 mm, it width being 8 to 10 mm, and its radius of curvature being about 200 mm. The rod 1 may be set in soft tissues without their dissection by being pushed through

the soft tissues longitudinally of the spine 2. To make this possible, both ends 4 of the flat rod 1 are made of a tapering shape, with the side surface of the end portion 4 on the convex side being the continuation of the surface of the rod 1, while the surface on the concave side defines a bevel merging with the rest of the surface on the concave side.

The device for fixing the rod 1 on the spine 2 includes two combs 5 with pointed teeth, adapted to retain the spine 2 in the frontal plane. The combs 5 are arranged at the ends of the rod 1 at its convex side and have their teeth facing the rod 1. The combs 5 are connected with the rod 1 with aid of braces 6. One end of each brace 6 has secured thereto by a threaded connection the stem 7 of the comb 5, while the other end of the brace 6 carries a clamp 8 engaging the rod 1 by its bent end. This end of the brace 6 is also threaded to receive a nut 9 which is rotatable to adjust the effort of straightening the spine 2.

The ends 4 of the rod 1, having the tapering shape, have made therein oblong holes 10. One of the holes 10 receives a screw 11 with the head having a tapered shape with the rounded tip. This end 4, with the rod 1 set against the spine 2, is the cranial one and is rigidly fixed to the spine 2. The other end 4, with the rod 1 set against the spine 2, is the caudal one and is fixed to the spine 2 with provisions for its displacement longitudinally of the spine 2, as the child grows. The rod 1 is positioned to one side of the spinous processes 3, while the combs 5 are placed to the opposite side of these spinous processes 3. Thus, the combs 5 take part in the fixation of the spine 2 in the frontal plane. On the end portion 4 which is the cranial one, the brace 6 of the comb 5 is secured with aid of the clamp 12 engaging the screw 11 by its bent end, to tbe gripped between the head of this screw 11 and the tapering end portion 4 of the rod 1. In this way rigid fastening of the end portion 4 - the cranial one - is provided for. To secure the caudal end portion 4 for displacement longitudinally of the spine 2, the clamp 8 is made to engage the rod 1. Alternatively, the cranial end portion 4 may be likewise secured with aid of the clamp 8 arranged to abut against the enlarged tapering portion of this end 4. To provide for elongation of the rod 1, the screw 11 may be set into the hole 10 in the caudal end 4 of the rod 1, with the brace 6 of the comb 5 being secured with aid of the clamp 12 positioned to define between its edge and the head of the screw 11 a distance providing for the longitudinal displacement of the rod 1 relative to the spine 2, as the child grows.

The length of the comb 5 is such that when it is set lengthwise of the spine 2, it engages at least two spinous processes 3; preferably, the length of the comb 5 is about 85 mm. The teeth of the comb 5 are pointed to easily enter the spinous processes 3. Preferably, the number of the teeth of the comb 5 is eight, the teeth being spaced so that each spinous process 3 along with the comb 5 is positioned should have one or two teeth piercing it.

To secure the spine 2 in the sagittal plane, the device for fixing the rod 1 includes two hooks 13 fastened to the ends 4 of the rod 1. With the rod 1 being fixed, the hook 13 engages the arch 14 (Figure 2) of the respective vertebra. The hook 13 has a groove 15 (Figure 3) complementary to the edge of the rod 1, and its threaded stem 16 carries a clamp 17 and a nut 18 rotatable to move and secure the clamp 17 as the rod 1 is being secured on the spine 2. For treatment of scoliosis, the rod 1 is positioned for its convex side to face the spinous processes 3 (Figure 4). To treat kyphoscoliosis, the rod 1 (Figure 5) is turned relative to the spinous processes 3. For kyphosis treatment, the rod 1 (Figure 1) has its convex side facing the archs 19. In both last-mentioned cases, the combs 5 and hooks 13 are secured on the screws 11 for rotation about the rod 1, the fixation of the spine 2 in the sagittal plane being attained by two hooks 13 (Figure 7) turned in the opposite directions and engaging the archs 19 of the adjacent vertebrae, as the rod 1 is being secured. In cases of spine fractures with kyphotic deformation, the rods 1 are positioned similarly to the kyphosis cases, the length of the rod 1 being dependent on the distance between the broken vertebrae. Thus, the proposed design of the device for fixing the rod 1 enables to distribute the effort straightening the spine 2 among several vertebrae, to reduce the load applied to each bone structure and to step up the effort of straightening the spine 2 while precluding destruction of the bone structures.

In cases where the spine 2 is curved to a great degree, it is expedient to employ paired combs to secure the rod 1, i.e. in one of its embodiments the device for fixing the rod 1 additionaly includes auxiliary combs 20 (Figure 8) in a number equalling that of the main combs 5, the combs 20 likewise having pointed teeth and being placed intermediate the rod 1 and the respective main comb 5 for their teeth to face one another, each comb 20 being secured on the brace 6 of the respective main comb 5. As the rod 1 is being positioned, the auxiliary combs 20 are placed to the same side of the spinous processes 3 to which the rod 1 itself is placed, to be moved along the brace 6 by rotation of the nut 21.

When the spinal curvature is as great as 50° according to Cobb or even greater, it is expedient to set at the apex of the curvature an additional pair 22 (Figure 9) of combs, with its brace 6 being secured to the rod 1 at the central portion thereof. To make the treatment even more effective, preliminary correction of the spinal curvature may be performed. To do this, special design adaptors (not shown) may be screwed onto the threaded ends of the braces 6 for attachment of either Kirschner wires, or else nylon cords (conventionally shown in the drawing with arrow lines) extending outwardly at the sides of the patient's body, to be secured to external apparatus of a known per se suitable type, e.g. a Latypov-Akberov apparatus.

To advance the rod 1 by the enclosed technique in the patient's body longitudinally of the spine 2, there are made two incisions 23 (Figure 10) and 24, and a special-design handle is 25 screwed into the hole 10 of that end portion 4 which is the caudal one, to be used to push the rod 1 through the soft tissues. As the rod 1 is being secured, the nuts 9 (Figure 11) are tightened until the spine 2 is straightened.

The implantable correctant of spinal curvature is set, as follows. X-ray pictures of the spine 2 (Figure 10) in the frontal and sagittal planes are consulted in advance to determine the positioning of the combs 5, i.e. the points of the operating incisions 23 and 24 are defined. The surgical operation is conducted with the patient lying on the belly, under narcosis. Curves of the spine 2 in the sagittal plane are straightened out by putting hard pillows or cushions under the belly or under the chest of the patient.

The incisions 23 and 24 are made, respectively, at the thoracic and lumbar parts of the spine 2 (Figure 1), at its convex side, longitudinally of the spinous processes 3. The length of each incision 23, 24 (Figure 10) need not be in excess of the length of the comb 5 (Figure 1). With the incisions made, the spine 2 is laid bare by separating the muscles. Then, hooks 13 (Figures 2 and 3) are led to underlie the archs 14 of the respective vertebrae, one hook in each one of the thoracic and lumbar incisions 23, 24 (Figure 10), respectively.

Then, in the incisions 23 and 24, muscles are separated from the spinous processes 3 (Figure 1) at the concave side of the spine 2, and in the incision 23 the comb 5 is set, and the brace 6 is turned into the stem 7. With low spinous processes the brace 6 is placed above the processes 3, and with high spinous processes 3 the brace 6 is guided either through the process 3 or through the space between the adjacent processes.

The next and very important stage of the surgical operation is setting the rod 1. In advance, the screw 11 (Figure 10) is turned into the hole 10 in one tapering end 4 of the rod 1, and the handle 25 is turned into the hole 10 in the opposite end 4. The rod 1 of the correctant is then guided either from the lower incision 24 into the upper incision 23, or vice versa, with the head of the screw 11 spreading the muscles in the blunt manner. As the rod 1 is being guided, it is set in the groove 15 (Figures 3 and 4) of the hook 13, under the brace 6 of the comb 5. Then the clamp 12 (Figure 1) is set onto the brace 6 of the comb 5, to be followed by the nut 9, and the clamp 17 (Figure 3) is set onto the stem 16, to be followed by the nut 18. Then the nuts 18 and 9 (Figure 1) are rotated to rigidly secure the cranial end 4 of the rod 1 to the spine 2, with the rod 1 (Figure 4) in scoliosis cases extending in the saggital plane, and the teeth of the combs 5 piercing the spinous processes 3 at their bases. The excessive lengths of the stem 16 and of the brace 6 are cut off with cutting pliers.

At the lumbar part, in the incision 24 (Figure 10), the securing of the caudal end 4 of the rod 1 is performed in the same sequence of steps. However, the tightening of the nuts 9 and 18 should be such that the rod 1 could slide upwardly relative to the spine 2 in the clamp 8 (Figure 4) and in the groove 15 (Figure 13) of the hook 13, as the child grows. Moreover, the clamp 8 and the hook 13 (Figure 1) should be positioned on the rod 1 at such distance from the adjacent end 4 of the rod 1, which is not short of the foreseeable elongation of the spine 2 of the child up to the puberty period. With the rod 1 secured, the spine 2 (Figure 11) becomes straightened already on the operating table.

Then the incisions 23 and 24 are sutured layer-wise. The straightening action of the correctant upon the spine 2 is being exerted up to the moment when the correctant is removed, accompanied by the directed growth of the bone structures of the spine 2 and straightening of the latter, owing to the more intense growth of the vertebrae at the concave side of the spine 2 and the inhibition of their growth at the convex side.

With the patient's growth ceasing, the rod 1 (Figure 1) is removed by the enclosed technique, with the bevel of the tapering end portion 4 of the rod 1 enabling to withdraw the rod 1 by merely pushing aside the soft tissues.

When the rod 1 is set for kyphoscoliosis treatment, the surgical operation is conducted in the same sequence, but, in order to provide for turning the rod 1 (Figure 5) relative to the longitudinal axis of the spine 2, the clamps 12 (Figure 7) of the combs 5 and the clamps 17 of the hooks 13 are made to engage the screws 11 received in the holes 10 provided in both ends 4 of the rod 1. To enhance the rigidity of the fixation of the rod 1, two hooks 13 are used. Thus positioned, the rod 1 exerts action simultaneously on the sagittal and frontal curvature of the spine 2.

With the curvature of the spine 2 equal to or exceeding 50° according to Cobb, the rod 1 is secured with three pairs 22 (Figure 9) of the combs 5 and 20 employed and arranged at three levels, viz. at the thoracic and lumbar ones and at the apex of the curvature. The surgical operation is conducted, as follows.

Three incisions are made: at the thoracic and lumbar parts of the spine 2 and at the apex of the curvature. The hooks 13 (Figure 7) are set, as it has been already described hereinabove, whereafter the combs 5, 20 (Figure 8) are set at both sides of the spinous processes, their teeth facing one another. The brace 6 is first introduced into the stem 7 of the comb 20 positioned at the convex side of the spine 2 and then screwed into the stem 7 of the comb 5 positioned at the concave side of the spine 2. The nut 21 is rotated to pull the comb 20 against the spinous processes 3, unit its teeth pierce the processes 3, and then the nut 9 (Figure 1) is rotated to pull the comb 5 positioned at the concave side of the spine 2. The next steps of securing the rod 1 are, as it has been described hereinabove.

In scoliosis cases with the curvature not in excess of 70° according to Cobb, when the rod 1 of the correctant can be still bent, the braces 6 (Figure 9) have attached thereto adaptors (not shown) with either wires or nylon cords being fastened to these adaptors, their free ends extending outside, to be fastened to a frame (not shown, either) for gradual lateral action upon the curved spine 2. With the necessary degree of correction attained, the wires or cords with the adaptors are removed.

In scoliosis cases with the angles of curvature in excess of 70° according to Cobb, when the rod 1 of the correctant would not be bent any further, lest the bone structures of the spine 2 might be destroyed, the surgery is conducted in two stages. First, the pairs 22 (Figure 9) of the combs 5, 20 and the hooks 13 are set at the three levels, and the curvature of the

spine 2 is corrected provisionally by the frame apparatus of the suitable known per se structure. At the second stage, with the necessary degree of correction of the spine 2 attained, the rod 1 is implanted.

In case of operations dealing with kyphotic spinal curvatures, the rod 1 is set in the frontal plane.

For treating new and inveterate spinal fractures accompanied by kyphotic deformation, the rod is secured in the same manner as in the kyphosis cases, but the rods used are shorter.

Clinical testing

15 patients 7 to 16 years of age, representing third-degree advancing cases of scoliosis of the thoracic and thoracic-lumbar parts of the spine, i.e. with the curvature angle within 50° according to Cobb, were subjected to surgical operations of setting the implantable correctant of spinal curvature. The older children had the rod fixed with the use of two combs and hooks set at the ends of the rod. In the cases of children 8 to 11 years of age, with unfixed forms of scoliosis, it was considered sufficient to set a pair of combs at each end of the rod, at the concave and convex sides of the spine.

In three cases with the spinal curvature angle in excess of 50°, the third pair of the combs was set at the apex of the curvature. In the postoperative period of frame apparatus was employed to pull the spine by Kirschner wires for its straightening. Then the apparatus was removed, and the successive fixation of the spine was effected by the implantable correctant.

In cases of scoliotic spinal curvature with the curvature angle in excess of 70° according to Cobb, first, three pairs of combs were implanted to be used for extending the spine and straightening it in the frame apparatus, and then the correctant rod was implanted.

The operations of implanting the correctant took 1 to 2 hours, depending on the degree of the curvature. All the patients endured the operation sufficiently well; there were no complications. They were able to leave their beds on the third or fourth day, and, on the ninth or tenth day following the removal of the sutures, they were able to leave the hospital for home. Schoolchildren were able to attend classes at their local schools; there was no need for them to use either plaster-of-Paris or removable correcting jackets.

CLAIMS

1. An implantable correctant of spine curvature, made of a resilient material in the form of a single flat rod of an arcuate shape, positionable with its convex side facing the convexity of the spine, to one side of the spinous processes, and securable on the spine with aid of a fixing device, so that the correctant is at least partly straightened to impart an effort straightening up the spine.

2. An implantable correctant of spinal curvature, as claimed in Claim 1, wherein either one or both end portions of the flat rod are of a tapering shape, the surface of the end portion on the convex side being the continuation of the convex surface of the rod, and the surface on the concave side having a bevel merging with the concave surface of the rest of the rod.

3. An implantable correctant of spinal curvature, as claimed in Claims 1 and 2, wherein the device for fixing the rod includes two combs arranged at the ends of the rod at the convex side thereof, with their teeth facing the rod, and braces in a number corresponding to that of the combs, for adjustment of the spine-straightening effort, each brace having one its end connected with the rod and its other end connected with the respective comb.

4. An implantable correctant of spinal curvature, as claimed in Claim 3, wherein the device for fixing the rod includes auxiliary combs in a number corresponding to that of the main combs, arranged intermediate the rod and the respective main combs with their teeth facing the teeth of the main combs, and secured on the braces of the respective main combs.

5. An implantable correctant of spinal curvature, as claimed in Claims 1 to 4, wherein the device for fixing the rod includes on each end portion of the rod either one or two hooks mounted each to engage the arch of the respective vetrebra.

6. An implantable correctant of spinal curvature, as claimed in claims 2 to 5, wherein the ends of the rod, having the tapering shape, have made therein oblong holes, the device for fixing the rod including screws receivable in these holes, the braces being secured directly on these respective screws for rotation about the rod.

7. An implantable correctant of spinal curvature, as claimed in Claims 1 to 6, wherein the device for fixing the rod comprises an additional pair of combs extending parallel with the rod at the convex side of the central portion thereof, and a brace having one its end attached to the rod, the combs of the additional pair being mounted on said brace with their teeth facing one another.

8. An implantable correctant of spinal curvature, as claimed in any one of the preceding Claims, substantially as hereintofore described with reference to the appended drawings.

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